



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,356	03/26/2004	Joseph G. Furst	ICON 2 13110-1	1250
27885	7590	10/16/2009	EXAMINER	
FAY SHARPE LLP			BUI, VY Q	
1228 Euclid Avenue, 5th Floor				
The Halle Building			ART UNIT	PAPER NUMBER
Cleveland, OH 44115			3773	
			MAIL DATE	DELIVERY MODE
			10/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/810,356	Applicant(s) FURST, JOSEPH G.	
	Examiner Vy Q. Bui	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 89-141 is/are pending in the application.
- 4a) Of the above claim(s) 91, 94, 97, 102, 103, 110, 111, 129, 132-138 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 89,90,92,93,95,96,98-101,104-109,112-128,130,131 and 139-141 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/28/08;12/5/08;8/28/09</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3773

DETAILED ACTION

Election/Restrictions

Claims 91, 94, 97, 102, 103, 110, 111, 129, 132-138 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 133-134 are directed to non-elected invention (body treated with radiation). Election of the body member made of a biodegradable material was made **without** traverse in the reply filed on 6/3/2009.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 104-108 recites the limitation "said stent" in line 2 of each claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 3773

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 89-90, 104-109, 112-128 are rejected under 35 U.S.C. 102(e) as being anticipated by Machan et al.-US2002/0065546 A1.

As to claims 89-90, 104-109, 112-128, Machan et al.-US2002/0065546 A1 (Abstract; sections [0015], [0016], [0030]-[0032], [0046]-[0048], [0075], [0080] and claims 8, for example) discloses stent grafts including bioactive agent, such as a GM-CSF or microcrystals of monosodium urate monohydrate (see [0016], [0030]), or taxol (see [0046]), intermediate compound such as a biodegradable PLA/a PLGA-MePEG/a poly lactide co-glycolide (see [0015], [0031], [0048]) or ethylene acrylic acid, which is a hydrophobic and hydrophilic compound (see [0032]).

Notice that as defined in the specification, the terms stent and graft are interchangeable (page 2, line 15), therefore, a stent and a graft are considered as the same devices or equivalent devices.

2. Claims 130-131 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz et al-6,368,658 B1.

As to claims 130-131, Schwartz et al-6,368,658 B1 discloses coating a medical device, such as a catheter, a stent graft, a stent of a metal or a polymeric material (col. 3, line 41 to col. 4, line 14) with a radiopaque material for fluoroscopic visualization (col. 1, lines 13-33) and/or with a biodegradable polymer coating (col. 6, lines 37) including bioactive agents such as

Art Unit: 3773

trapidil (col. 4, line 65), rapamycin (col. 4, line 37) or paclitaxel (col. 4, line 45) for a treatment at a body location.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 104-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Machan et al.-US2002/0065546 A1.

As to claims 104-109, Machan-'546 explicitly disclose a coating of a bioactive agent on a graft. However, as admitted by the Applicant, a stent is used interchangeably to a graft (specification: page 2, line 15). It would have been obvious to one of ordinary skill in the art to interchange a graft as disclosed by Machan-'546 for a stent, for a stent and a graft are considered the same devices or at least equivalent devices as admitted by the Applicant.

2. Claims 92-93, 95-96, 98-101, rejected under 35 U.S.C. 103(a) as being unpatentable over Machan et al.-US2002/0065546 A1 in view of Kunz et al.-6,515,009 B1.

As to claims 224-225, Ashton -'598 discloses substantially the claimed invention, except for a trapidil and GM-CSF as biological agents. However, trapidil and taxol are well known biological agents. For example, Kunz-'009 (col. 17, lines 2-7) discloses trapidil as a favorable cystostatic agent for inhibiting cell growth and division and taxol (col. 5, lines 21-27) for treatment of pathologically proliferating normal tissue. It would have been obvious to one of ordinary skill in the art to provide trapidil and taxol to Machan et al.-US2002/0065546 A1's stent

Art Unit: 3773

graft as these agents will inhibiting cell growth and division and prevent a proliferation of normal tissue in a blood vessel and therefore preventing a restenosis at the location of the stent graft in a blood vessel.

3. Claims 130-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Machan et al.-US2002/0065546 A1 in view of Schwartz et al-6,368,658 B1.

As to claims 130-131, Machan et al.-US2002/0065546 A1 discloses substantially the claimed invention, except for a trapidil and GM-CSF as biological agents. However, trapidil and taxol are well known biological agents. For example, Schwartz et al-6,368,658 B1 (col. 17, lines 2-7) discloses trapidil as a vascular cell growth inhibitor and rapamycin for blocking smooth muscle cell proliferation. It would have been obvious to one of ordinary skill in the art to provide trapidil and rapamycin to Machan et al.-US2002/0065546 A1's stent graft as these agents will inhibiting cell growth and prevent a proliferation of tissue in a blood vessel and therefore preventing a restenosis at the location of the stent graft in a blood vessel.

4. Claims 139-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al-6,368,658 B1.

As to claims 139-141, Schwartz et al-6,368,658 B1 discloses coating a medical device, such as a catheter, a stent graft, a stent of a metal or a polymeric material (col. 3, line 41 to col. 4, line 14) with a radiopaque material for fluoroscopic visualization (col. 1, lines 13-33) and/or with a biodegradable polymer coating (col. 6, line 37) including bioactive agents such as trapidil (col. 4, line 65), rapamycin (col. 4, line 37) or paclitaxel (col. 4, line 45) for a treatment at a body location. Schwartz et al-6,368,658 B1 discloses substantially the claimed invention, except for the body member is made of a biodegradable material. However, a stent of a biodegradable material, such as a PGA, is well known in the art. It would have been obvious to one of ordinary

Art Unit: 3773

skill in the art to make a Schwartz et al-6,368,658 B1's stent of a biodegradable material such as a PGA as this material is well known material suitable for making a stent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vy Q. Bui/
Primary Examiner, Art Unit 3773